

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3541. Misbranding of Sulfa Salverol ointment. U. S. v. 8,148 Tubes * * *.
(F. D. C. No. 15287. Sample No. 6315-H.)

LIBEL FILED: February 19, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about July 10 and 17 and August 9, 1944, from Newark, N. J., by Day Chemical Co., Inc.

PRODUCT: 8,148 tubes of *Sulfa Salverol ointment* at New York, N. Y.

LABEL, IN PART: "Contains: Sulfanilamide 4%, Sulfathiazole 3%, with Oil of Cade, Calamine, and Menthol combined in a specially Prepared absorption base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying circular entitled "New Sulfa Formula Works Wonders on the Home Front!" were false and misleading. The statements represented and suggested that the article was effective as a remedy in many stubborn skin diseases; that it would permit natural healing; and that it would be efficacious in the treatment of eczema, dermatitis, athlete's foot, acne, psoriasis, skin rashes, pimples, scabies, scalp seborrhea, sores, barber's itch, insect bites, abrasions, cuts, and minor burns. The article was not an adequate treatment for the conditions mentioned, and it would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods and duration of administration or application since there were no warnings to the effect that the article may produce a sensitivity to sulfonamides, preventing their subsequent use in serious conditions for which those drugs could have been life-saving, or that the article should not be used on persons with known sensitivity to the sulfonamides.

Section 505 (a), the article was a new drug within the meaning of the law, and no application filed pursuant to the law was, or had been, effective with respect to the article.

DISPOSITION: March 2, 1945. The Research Drug Co., Inc., New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3542. Action to enjoin and restrain the interstate shipment of misbranded Gingisol. U. S. v. David J. Barben (Gingisol Laboratories). (Inj. No. 196.)

COMPLAINT FILED: June 28, 1948, Northern District of Ohio, against David J. Barben, trading as Gingisol Laboratories, Cleveland, Ohio.

NATURE OF CHARGE: That the defendant had been and was at the time of filing the complaint introducing and causing the introduction into interstate commerce, at Cleveland, Ohio, consignments of a drug designated as *Gingisol*, consisting of a solution of phenol and alkali in flavored, perfumed, colored water;

* See also No. 3541.